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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,475	11/20/2001	Vladislav Olchanski	58367.000003	2706

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EXAMINER
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TANG, KAREN C

ART UNIT	PAPER NUMBER
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2151

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/996,475	Applicant(s) OLCHANSKI ET AL.	
	Examiner Karen C. Tang	Art Unit 2151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/14/02</u> . | 6) <input type="checkbox"/> Other: _____  |

### **Response to Arguments**

1. Claims 1-25 have been examined.
2. Applicant's arguments filed 11/9/05 have been fully considered but they are not persuasive.
3. The affidavit filed on 11/9/05 under 37 CFR 1.131 has been considered but is ineffective to overcome the Menzie et al. reference.
4. Applicant is attempt to prove the invention by showing conception before May 15, 2000 (the effective data of Menzie) before that date until Nov 20, 2001, the date of filing of this application.
5. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Menzie reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The exhibit does not demonstrate the evidence or proof in showing that the claimed conception took place.

### I. >< GENERAL REQUIREMENTS

The essential thing to be shown under 37 CFR 1.131 is priority of invention and this may be done by any satisfactory evidence of the fact. FACTS, not conclusions, must be alleged. Evidence in the form of exhibits may accompany the affidavit or declaration. Each exhibit relied upon should be specifically referred to in the affidavit or declaration, in terms of what it is relied upon to show. For example, the allegations of fact might be supported by submitting as evidence one or more of the following:

- (A) attached sketches;
- (B) attached blueprints;
- (C) attached photographs;
- (D) attached reproductions of notebook entries;
- (E) an accompanying model;
- (F) attached supporting statements by witnesses, where verbal disclosures are the evidence relied upon. *Ex parte Ovshinsky*, 10 USPQ2d 1075 (Bd. Pat. App. & Inter. 1989);
- (G) testimony given in an interference. Where interference testimony is used, the applicant must point out which parts of the testimony are being relied on; examiners cannot be expected to search the entire interference record for the evidence. *Ex parte Homan*, 1905 C.D. 288 (Comm'r Pat. 1905);
- (H) Disclosure documents (MPEP § 1706) may be used as documentary evidence of conception.

Exhibits and models must comply with the requirements of 37 CFR 1.91 to be entered into an application file. See also MPEP § 715.07(d).

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A general allegation that the invention was completed prior to the date of the reference is not sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883). Similarly, a declaration by the inventor to the effect that his or her invention was conceived or reduced to practice prior to the reference date, without a statement of facts demonstrating the correctness of this conclusion, is insufficient to satisfy 37 CFR 1.131. 37 CFR 1.131(b) requires that original exhibits of drawings or records, or photocopies thereof, accompany and form part of the affidavit or declaration or their absence satisfactorily explained. In *Ex parte Donovan*, 1890 C.D. 109, 52 O.G. 309 (Comm'r Pat. 1890) the court stated

If the applicant made sketches he should so state, and produce and describe them; if the sketches were made and lost, and their contents remembered, they should be reproduced and furnished in place of the originals. The same course should be pursued if the disclosure was by means of models. If neither sketches nor models

are relied upon, but it is claimed that verbal disclosures, sufficiently clear to indicate definite conception of the invention, were made the witness should state as nearly as possible the language used in imparting knowledge of the invention to others.

However, when reviewing a 37 CFR 1.131 affidavit or declaration, the examiner must consider all of the evidence presented in its entirety, including the affidavits or declarations and all accompanying exhibits, records and "notes." An accompanying exhibit need not support all claimed limitations, provided that any missing limitation is supported by the declaration itself. *Ex parte Ovshinsky*, 10 USPQ2d 1075 (Bd. Pat. App. & Inter. 1989).

The affidavit or declaration and exhibits must clearly explain which facts or data applicant is relying on to show completion of his or her invention prior to the particular date. Vague and general statements in broad terms about what the exhibits describe along with a general assertion that the exhibits describe a reduction to practice "amounts essentially to mere pleading, unsupported by proof or a showing of facts" and, thus, does not satisfy the requirements of 37 CFR 1.131(b). *In re Borkowski*, 505 F.2d 713, 184 USPQ 29 (CCPA 1974). Applicant must give a clear explanation of the exhibits pointing out exactly what facts are established and relied on by applicant. 505 F.2d at 718-19, 184 USPQ at 33. See also *In re Harry*, 333 F.2d 920, 142 USPQ 164 (CCPA 1964) (Affidavit "asserts that facts exist but does not tell what they are or when they occurred.").

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6. The declaration filed on 11/9/05 fails to provide evidence to support the indicated claim of conception prior to the effective date of the Menzie reference. The evident is not clear to satisfy issues of conception as well as diligence.

7. The evidence submitted is insufficient to establish diligence from a date of conception to an actual reduction to practice. There is no information provided in the exhibits explicitly demonstrate diligence applied to reduce the method to practice.

Under 37 CFR 1.131, the critical period in which diligence must be shown begins just prior to the effective date of the reference or activity and ends with the date of a reduction to practice, either actual or constructive (i.e., filing a United States patent application). Note, therefore, that only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon" is not relevant to an affidavit or declaration under 37 CFR 1.131. See *Ex parte Merz*, 75 USPQ 296 (Bd. App. 1947). Form paragraph 7.62 (reproduced in MPEP § 715) may be used to respond to a 37 CFR 1.131 affidavit where diligence is lacking.

The included Declaration fails to properly describe the events/dates between alleged conception (prior to May 15, 2000) and indicated Actual Reduction to Practice (November 21, 2001).

6. Regards with the 101 rejection, claims 1-9, 11-17 fail to set forth the operation of the claimed elements are tangible embodied on an article of manufacture. The applicant does not demonstrate a "clearly directed to practical applications that produce a useful concrete and tangible result", in the argument.

Referring back to claims 10, 18, and 25, signal embodied a carrier wave is still ineligible for patent protection because they do not fall within any of the four statutory classes.

See New Guidelines.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-9, and 11-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter (The claims fail to set forth the operation of the claimed elements are tangible embodied on an article of manufacture. See New Guidelines)

Claims 10, 18 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter (signal embodied a carrier wave is still ineligible for patent protection because they do not fall within any of the four statutory classes. See New Guidelines)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Menzie et al hereinafter Menzie (US 6,650,932).

1. Referring to Claims 1, 11, 24, and 25, Menzie discloses collecting at least two outcomes data sets (refer to Col 1, Lines 30-50);  
At least one processor readable carrier (refer to Col 5);  
Instructions carried on the at least one carrier (it is inherent that software comprises instructions, refer to Col 5);  
Wherein the instructions are configured to be readable from the at least one carrier by at least one processor and thereby cause the at least one processor to operate so as to (refer to Col 4, Lines Col 5 and Col 18, Lines 35-55):  
Converting the at least two outcomes data sets into at least one outcomes result (test results, refer to Col 2, Lines 8-30).  
Establishing a norm for an outcomes data group, the outcomes data group comprising a plurality of the at least two outcomes data sets (refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35).  
Comparing a selected one of the at least one outcomes result to the norm (refer to Col 6, Lines 60-67, and Col 7, Lines 1-30);  
Generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (refer to Col 5 - 9).

2. Referring to Claim 19, Menzie discloses



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A data collection portion wherein the data collection portion collects at least two outcomes data sets (refer to Col 4, Lines 15-67)

A data processor portion wherein the data processor portion receives the at least two outcomes data sets from the data collection portion and wherein the data processor (refer to Col 4 and 5) comprises:

A converter portion wherein the converter portion converts the at least two outcomes data sets into an at least one outcomes result (test results, refer to Col 2, Lines 8-30);

A norm establishing portion wherein the norm established portion establishes a norm for an outcomes data group, the outcomes data group comprising a plurality of the at least two outcomes data sets (refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35).

A comparison portion wherein the comparison portion compares a selected one of the at least one outcomes result to the norm (refer to Col 6, Lines 60-67, and Col 7, Lines 1-30);

and a report generation portion wherein the report generation portion generates at least one outcomes monitoring report comprising the at least one outcomes result and the norm (refer to Col 5 – 9);

3. Referring to Claims 2 and 12, Menzie discloses transmitting the at least two outcomes data sets to a data processor (refer to Col 2, Lines 8-31, Col 4, Lines 50-67).

4. Referring to Claims 3, 13, and 21, Menzie discloses selectively restricting access to the outcomes monitoring report (refer to Col 11, Lines 5-30).
5. Referring to Claims 4, and 14 and 20, Menzie posting the outcomes monitoring report over the webpage (refer to Col 4 and 6).
6. Referring to Claims 5 and 16, Menzie discloses collecting the at least two outcomes data sets from at least one user entity at a plurality of discrete intervals (refer to Col 1, Col 2, Col 11, Lines 1-60, and Col 13, 14, and 16).
7. Referring to Claim 7, Menzie discloses generating the outcomes report from at least two of the plurality of discrete intervals (refer to Col 5 – 9, Col 1, 2, 11, Lines 1 – 60 , and Col 13, 14, and 16).
8. Referring to Claims 8 and 16, Menzie discloses collecting the outcomes data sets from a plurality of user entities (refer to Col 11, and Col 17), individually identifying and converting the outcomes data sets for each user entity of the plurality of user entities (refer to Col 11, Col 13, and 14), and wherein the outcomes data sets from the plurality of user entities comprises the outcomes data group (refer to Col 11).

9. Referring to Claim 9 and 17, Menzie discloses wherein the outcomes monitoring report includes at least one outcomes result for a selected user entity of the plurality of user entities and at least one comparison of the norm to the selected one of the least one outcomes result for the selected user entity (refer to Col 5, 6, 7, 10, 14, 16, and 17).
10. Referring to Claim 10 and 11, Menzie discloses a computer signal embodies in a carrier wave readable by a computing system and encoding a computer program of instructions for executing a computer process performing the method recited in claim 1 (refer to Col 5, 12, 13, 15, and 18).
11. Referring to Claim 22, Menzie discloses wherein the at least two outcomes data sets are surgical procedures outcomes data set (refer to Col 1 and 2).
12. Referring to Claim 23, Menzie discloses wherein the at least two surgical procedures outcomes dataset are primary source data sets (refer to Col 1 and 2).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen C. Tang whose telephone number is (571)272-3116. The examiner can normally be reached on M-F 7 - 3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zarni Maung can be reached on (571)272-3939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Tang

LARRY D. DONAGHUE  
PRIMARY EXAMINER

